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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/765,739 | 01/18/2001 | Robert Lawton | 00-1278 | 9509 |

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EXAMINER

FORD, VANESSA L

ART UNIT

PAPER NUMBER

1645

DATE MAILED: 12/20/2001

7

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|------------------------------|------------------------|---------------------|--|
| | 09/765,739 | LAWTON ET AL. | |
| Examiner | Art Unit | | |
| Vanessa L. Ford | 1645 | | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 18 January 2001.

2a) This action is **FINAL**. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-34 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) _____ is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claims 1-34 are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are objected to by the Examiner.

11) The proposed drawing correction filed on _____ is: a) approved b) disapproved.

12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

15) Notice of References Cited (PTO-892) 18) Interview Summary (PTO-413) Paper No(s). _____
16) Notice of Draftsperson's Patent Drawing Review (PTO-948) 19) Notice of Informal Patent Application (PTO-152)
17) Information Disclosure Statement(s) (PTO-1449) Paper No(s) 20) Other: _____

DETAILED ACTION

Election/Restriction

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

Group I. Claims 1-2 and 25-28 are drawn to a composition comprising an isolated polypeptide classified in class 530, subclass 300. Further election of one SEQ.ID.NO required.

Group II. Claims 3-20 are drawn to a method of detecting the presence of antibodies classified in class 435, subclass 7.32.

Group III. Claims 21-24 are drawn to a device, class 435, subclass 283.1.

Group IV. Claims 29-33 are drawn to a method of diagnosing an *Ehrlichia* infection, class 424, subclass 93.4.

Group V. Claim 34 is drawn to an antibody, class 530, subclass 387.1.

2. Groups I, III and V are related as different products. Group I is drawn to a composition comprising an isolated polypeptide. Group III is drawn to a device. Group V is drawn to an antibody. Group I and III differ because they are physically and functionally distinct chemical entities. These products are distinct because they differ structurally and functionally. Moreover, the products of Groups I and V can be contained in a different device or container such as an ampoule, an IV catheter, or premixed autoinjector.

3. Groups I and (II and IV) are product and process of using. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a material different process of using that product (MPEP 806.05(h)). In the instant case the polypeptides of Group I, can be used to in assays to identify compounds.

4. Groups II and IV are related as different methods. Group II is drawn to a method of detecting the presence of antibodies. Group IV is drawn to a method of diagnosing an *Ehrlichia* infection. They differ because they have different goals, require different method steps and parameters.

5. Groups III and (II and IV) are unrelated. The product of Group III is not required for the methods of Groups II and IV. Therefore, they are materially distinct and independent from each other as claimed.

6. Groups V and (II and IV) are product and process of using. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a material different process of

using that product (MPEP 806.05(h)). In the instant case the antibodies of Group V, can be used in affinity assays.

DISTINCT INVENTIONS

7. Group I contains claims 1-2 and 25-28 reciting a Markush group containing a plurality of disclosed patentably distinct inventions with distinct SEQ.ID.NOS 1-7. Applicant is advised to elect one SEQ.ID.NO from Group I. Applicant is required under 35 U.S.C. 121 to elect a single disclosed SEQ.ID.NO and associated sequence which share the common structure or overlap the sequence of that SEQ.ID.NO with specific amino acid.

8. Restriction to one of the following inventions is required under 35 U.S.C. 121: The inventions are distinct, each from the other because of the following reasons: Because these inventions are distinct for the reasons given and have acquired a separate status in the art because of their recognized divergent subject matter as shown by their different classification, restriction for examination purposes as indicated is proper. Moreover, in the absence of restriction it would place an undue search and examination burden on the examiner.

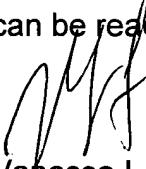
9. Applicant is advised that the reply to this requirement to be complete must include an election of invention to be examined even though the requirement be traversed (37 CFR 1.143).

10. Applicant is reminded that upon that upon cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. 1.48(b) and by the fee required under 37 C.F.R. 1.17(h).

11. Any inquiry of the general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Papers relating to this application may be submitted to Technology Center 1600, Group 1640 by facsimile transmission. The faxing of such papers must conform with the notice published in the Office Gazette, 1096 OG 30 (November 15, 1989). Should applicant wish to FAX a response, the current FAX number for the Group 1600 is (703) 308-4242.

Any inquiry concerning this communication from the examiner should be directed to Vanessa L. Ford, whose telephone number is (703) 308-4735. The examiner can normally be reached on Monday – Friday from 7:30 AM to 4:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached at (703) 308-3909.



Vanessa L. Ford
Biotechnology Patent Examiner
December 12, 2001



LYNETTE R. F. SMITH
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600